REMARKS

This is a response to the Final Rejection dated February 8, 2006, (hereinafter the "Final Rejection"). Claims 1, 4, 12, 39 and 41 have been amended. Claim 6 has been canceled. Independent claim 1 has been amended to limit the claimed antioxidants to α-lipoic acid, chlorophyllin and glutathione.

Summary of Personal Interview

A personal interview was conducted on March 28, 2006, between applicant's representative, Kevin Dunleavy, and Examiners Yong S. Chong and Shengjun Wang. All claims were discussed during the personal interview. No exhibit was shown or demonstration conducted. The following prior art was discussed: U.S. Patent No. 6,162,801, issued to Kita (hereinafter "Kita"), Bissett, D.L. et al., *J. Soc. Cosmet. Chem.* **1992**, *43*, 85-92 (hereinafter "Bissett"), and Darr, D. et al., *British Journal of Dermatology* **1992**, *127*, 247-253 (hereinafter "Darr"), in view of Shimoi, K., et al., *Mutation Research* **1996**, *350*, 153-161 (hereinafter "Shimoi"), U.S. Patent No. 5,776,460, issued to Kim et al. (hereinafter "Kim"), copending U.S. Patent application no. 10/288,761; copending U.S. Patent application no. 10/279,315; U.S. Patent no. 5,141,741 (Ishida et al.); and U.S. Patent no. 5,650,137 (Nguyen et al.).

The proposed amendments that were discussed are identical to the amendments made in the present submission. The principal arguments discussed are set forth below in the response to the Final Rejection.

It was agreed at the personal interview that if the proposed amendments were entered, these amendments would overcome at least the first 35 U.S.C. 103(a) rejection that appears in the Final Rejection.

Entry of the Amendment

It is the applicant's position that the present amendment after Final Rejection should be entered either: (1) because it places the application in better form for appeal by overcoming at least one of the outstanding rejections, as agreed at the personal interview of March 28, 2006, or (2) because it does not raise new issues since the amendments merely narrow the claims by deletion of subject matter. All of the claimed subject matter remaining after the amendmenst

was already present in the previous set of claims that formed the basis for the Final Rejection. Accordingly, the amendment does not raise any new issues.

Provisional Double Patenting Rejections

Claims 1, 4-9 and 12-20 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of copending U.S. Patent application no. 10/288,761. No claims have been allowed in this copending application and thus the applicant would like to defer response to this rejection until one or more claims in the copending application are indicated as being allowable. Also, once the claims of the present application are otherwise allowable, for the reasons set forth below, this rejection should be withdrawn since there are no currently allowable claims in the copending application.

Claims 1, 4-9 and 12-20 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending U.S. Patent application no. 10/279,315. U.S. Patent application no. 10/279,315 has become abandoned. Accordingly, withdrawal of this rejection is requested.

Rejections under 35 U.S.C. § 103(a)

Claims 1-4, 7, 9-20, 38 and 38 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,162,801, issued to Kita (hereinafter "Kita"), Bissett, D.L. *et al.*, *J. Soc. Cosmet. Chem.* **1992**, *43*, 85-92 (hereinafter "Bissett"), and Darr, D. *et al.*, *British Journal of Dermatology* **1992**, *127*, 247-253 (hereinafter "Darr"), in view of Shimoi, K., *et al.*, *Mutation Research* **1996**, *350*, 153-161 (hereinafter "Shimoi") and U.S. Patent No. 5,776,460, issued to Kim et al. (hereinafter "Kim").

At the personal interview, it was pointed out by the applicant that:

(a) Kita does not disclose oral administration of a composition, as required by the claims,

(b) Kita uses vitamin D_3 as a sunblock to absorb UV radiation and thus does not teach the effectiveness of vitamin D_3 against radiation injury if the vitamin D_3 were orally ingested,

(c) The proposed amendments to claim 1 delete the materials taught by Bissett,

(d) The proposed amendments to claim 1 delete the materials taught by Darr et al.,

(e) The proposed amendments to claim 1 delete the materials taught by Shimoi et al.,

(f) Claim 1 does not require the materials taught by Kim et al., and

(g) None of the cited references specifically refers to treatment of an injury caused by one or more of proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation.

In view of these arguments and the proposed amendments, it was agreed at the personal interview that this rejection would be overcome upon entry of the amendments made in the present amendment (See the Examiner's Interview Summary Record). Accordingly, entry of the present amendment, favorable consideration and withdrawal of the rejection is requested.

Claims 5-6 and 39-41 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,162,801, issued to Kita (hereinafter "Kita"), Bissett, D.L. *et al.*, *J. Soc. Cosmet. Chem.* **1992**, *43*, 85-92 (hereinafter "Bissett"), and Darr, D. *et al.*, *British Journal of Dermatology* **1992**, *127*, 247-253 (hereinafter "Darr"), in view of Shimoi, K., *et al.*, *Mutation Research* **1996**, *350*, 153-161 (hereinafter "Shimoi"), U.S. Patent No. 5,776,460, issued to Kim et al. (hereinafter "Kim"), and further in view of U.S. Patent no. 5,141,741 (Ishida et al.) and U.S. Patent no. 5,650,137 (Nguyen et al.). This rejection is respectfully traversed and reconsideration is requested for the reasons which follow.

At the personal interview, it was pointed out that, with respect to claim 1, as amended by this amendment,

(a) None of the cited references specifically refers to treatment of an injury caused by one or more of proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation.

(b) Kita, Nguyen et al. and Ishida et al. do not disclose oral administration of a composition, as required by the claims,

(c) Kita uses vitamin D_3 as a sunblock to absorb UV radiation and thus does not teach the effectiveness of vitamin D_3 against radiation injury if the vitamin D_3 were orally ingested,

(d) Nguyen et al. and Ishida et al. use antioxidants to treat skin, scalp and mucosa by topical application directly to the area to be treated and thus do not give any indication of an expectation of success via oral administration of antioxidants,

(e) The proposed amendments to claim 1 delete the materials taught by Bissett,

(f) The proposed amendments to claim 1 delete the materials taught by Darr et al.,

(g) The proposed amendments to claim 1 delete the materials taught by Shimoi et al., and

(h) Claim 1 does not require the materials taught by Kim et al.

This rejection should be withdrawn for several reasons. First, the primary reference to Kita, which is the only reference relating to the use of vitamin D_3, does not teach or suggest use of vitamin D_3 to treat an injury caused by one or more of proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation. Instead, Kita relates to the use of vitamin D_3 as a sunblock to absorb UV radiation. This is significant because proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation are forms of ionizing radiation, whereas UV radiation is not. As the applicant demonstrated by submission of six publications on January 21, 2005, with a discussion thereof, ionizing radiation causes a different type of injury than UV radiation. Thus, a skilled person would not consider treatments for UV radiation to be applicable to injuries due to ionizing radiation since the injury being treated is different and thus there is no reason to expect a successful result from the treatment.

In addition, a skilled person would not employ vitamin D_3 as a blocking agent against ionizing radiation, based on the teaching in Kita to employ it as a sunblock against UV radiation since skilled persons are aware that although vitamin D_3 absorbs UV radiation, it does not absorb significant amounts of ionizing radiation. As a result, vitamin D_3 would not be considered useful as a blocking agent against ionizing radiation.

Third, Kita teaches topical use of vitamin D_3 for use to absorb UV radiation. The UV radiation is absorbed because the vitamin D_3 is located between the body and the source of radiation. The present claims relate to oral administration of the composition, in which case the vitamin D_3 is not located between the source of radiation and the body. As a result, the skilled person would have no expectation of success for oral administration of vitamin D_3 from the teachings of Kita, since Kita teaches that the vitamin D_3 should be between the source of radiation and the body in order to absorb the radiation and, in the case of oral administration, it is not.

The secondary references to Ishida et al. and Nguyen et al. relate to the use of antioxidants to treat skin which has been sunburned or damaged by, for example, UV radiation or atmospheric pollutants. Thus, the skilled person would not apply the teachings of Ishida et al. or Nguyen et al. in the present invention for at least two important reasons. First, the type of injury caused by forms of ionizing radiation, such as the claimed proton radiation, fluoroscopic radiation, alpha radiation, beta radiation and gamma radiation is different from the skin injury

caused by UV radiation, as discussed in the submission of January 21, 2005, and thus the skilled person would not conclude that a treatment for UV radiation would be effective to treat an injury due to the claimed forms of ionizing radiation. Second, Ishida et al. and Nguyen et al. only relate to the treatment of the skin, scalp and/or mucosa. The present invention requires oral administration of the composition. The skilled person would not conclude that a skin, scalp and/or mucosa treatment would be effective if administered orally. Stated otherwise, skilled persons would not ingest topical compositions with the expectation of successfully treating ionizing radiation injury since there is no indication in these references that the compositions would be effective if they were not applied in direct contact with the area to be treated, e.g. skin, scalp or mucosa.

For the foregoing reasons, favorable consideration and withdrawal of the rejection under 35 U.S.C. 103(a) and issuance of a Notice of Allowance are requested.

Best regards.

Respectfully submitted,

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